K121374

510(K) SUMMARY

Prepared in accordance with 21 CFR § 807.92

FEB 2 2 2013

Date Summary Prepared: February 22, 2013

Submitter Information:

Company Name: Deshum Medical
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Device Information:

Trade Name: Z1 Blower

Common Name: CPAP System

Classification Name: Non-Continuous (Respirator) Ventilator, 21 CFR § 868.5905

Device Class: Class II

Predicate Devices:

510(k) Number:	K100121
Manufacturer:	AEIOMed, Inc.
Product Name:	Model 300157 CPAP System
510(k) Number:	K052597
Manufacturer:	Hoffman Laboratories, LLC
Product Name:	Breathex Omega CPAP Device, Model 322
510(k) Number:	K013843
Manufacturer:	Resmed Corp.
Product Name:	Autoset Spirit CPAP System

Device Description: The Z1 Blower provides the patient with a continuous positive airway pressure (CPAP) flow ranging from 4-20 cmH_2O above ambient atmospheric pressure. The device consists of a flow generator and data interfaces. It is

intended for home use, and for prescription use only. Treatment settings (e.g., air pressure, ramp) are directed by the physician and can be modified by the physician.

Software utilized in both primary (control of pressure) and secondary (data collection and transfer) functions of the Z1 Blower is considered a Moderate Level of Concern.

Intended Use: Provides continuous positive airway pressure (CPAP) to support treatment of adults with obstructive sleep apnea.

Indications for Use: The Z1 Blower is a single patient reusable device that provides continuous positive airway pressure (CPAP) to support treatment of adults (over 30 kg) with obstructive sleep apnea.

Technological Characteristics:

The Z1 Blower consists of the main flow generator and accessories. The Z1 Blower and the identified predicate devices have the same fundamental technological characteristic: Use of a pneumatic pump to deliver continuous positive airway pressure within a clinically indicated therapeutic pressure range. Other technological characteristics are the same or very similar. Nonetheless, minor differences are present. Importantly, these minor differences do not raise different questions of safety and effectiveness, and acceptable scientific methods for evaluation exist. Applicable standards have been utilized to ensure that the Z1 Blower is as safe and as effective as the predicate device.

Performance Testing: Deshum Medical has performed the following performance testing to support the safety and effectiveness of the Z1 Blower:

Maximum temperature at the patient connection port under normal and single fault conditions was < 43 degrees C at a pressure setting of 20 cmH20;

Pressure stability under static long-term conditions was within ± 1.0 cmH2O of the set pressure of 10 cmH2O;

Short term static pressure accuracy: the actual pressure was within ± (0.6 cmH2O + 4% * set pressure) of the set pressure for all pressure settings;

Dynamic pressure stability: the peak to peak pressure

variation was between 0.6 and 3.1 cmH2O for all pressure and breathing rate settings, and was less than the variation of the predicate device for all pressure and breathing rate settings;

Maximum flow rate was ≥ 75 Liters per minute and ≥ the maximum flow rate of the predicate device for each pressure setting.

Acoustic noise testing found that the sound pressure level was ≤ 36dBA;

Ability of the system to detect air leaks: air leaks were detected within ±5 mmH20 of the specified air leak detection thresholds;

Volatile organic compounds: no volatile organic compounds were observed in the air output of the device above 5.0 ug per cubic meter;

Particulate matter: no particulate matter was observed in the output air of the device above 5.0 ug per cubic meter;

The Z1 Blower added no carbon monoxide or carbon dioxide to the output air and the ozone output of the device met the 21 CFR 801.415 requirement of 0.05 ppm or less.

The Z1 Blower complies with the following performance and safety standards: ISO 5356-1:2004 Anesthetic and Respiratory Equipment – Conical Connectors: Part 1: Cones and Sockets. ASTM F 1246-91 standard specification for Electrically Powered Home Care Ventilators, Part 1 – Positive-Pressure Ventilators and Ventilator Circuits. IEC 60601-1:2005 Medical Device Equipment – Part 1: General requirements for basic safety and essential performance. IEC 60601-1-2:2007 Medical Device Equipment – Part 1-2: General requirements for basic safety and essential performance – collateral standard: Electromagnetic compatibility – requirements and tests. ISO 23328-2:2002 Breathing system filters for anesthetic and respiratory use – part 2: non filtration aspects. ISO 17510-1:2007 Sleep apnoea breathing therapy– Part 1: Sleep apnoea breathing therapy equipment.

No clinical data was generated to support a substantial equivalence determination.

Conclusion:	The Z1 Blower is substantially equivalent to the predicate devices, as the devices share a common intended use, and technological differences between the Z1 Blower and the predicate do not raise new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 22, 2013

Deshum Medical
C/O Ms. Maureen O'Connell
President
O'Connell Regulatory Consultants, Incorporated
5 Timber Lane
NORTH READING MA 01864

Re: K121374
Trade/Device Name: ZI Blower
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: February 12, 2013
Received: February 13, 2013

Dear Ms. O'Connell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K 121374

Device Name: Z1 Blower

Indications for Use:

The Z1 blower is a single patient reusable device that provides continuous positive airway pressure (CPAP) to support treatment of adults (over 30 kg) with obstructive sleep apnea.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Lester W Schultheis Jr
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(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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